MAY 10 2013

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
NextStep Retrograde Catheters with Expanded Indications and Increased Lengths

1. **Submitter Information**

Name:	Arrow International, Inc (subsidiary of Teleflex Inc.)
Address:	2400 Bernville Road Reading, PA 19605-9607
Telephone Number:	(610) 378-0131
Contact Person:	Gwen Taschner Regulatory Affairs Associate
Telephone Number:	(610) 378-0131 Extension 603253
Fax Number:	(610) 478-3179
Email:	gwen.taschner@teleflex.com

Date Prepared: January 31, 2013

2. **Device Name**

Device Trade Name:	NextStep Retrograde
Common Name:	Chronic Hemodialysis Catheter
Classification Name:	Catheter, Hemodialysis, Implanted

3. **Predicate Devices**

Predicate 1: Arrow NextStep Antegrade Chronic Hemodialysis Catheter (K111900)

Predicate 2: Arrow NextStep Retrograde Chronic Hemodialysis Catheter (K111117)

4. **Device Description**

The NextStep Retrograde Chronic Hemodialysis Catheter (herein referred to as the proposed NSR catheter) is a long-term, single use catheter designed to provide access to the central venous system in a healthcare facility environment. The catheter is a two-piece, two-lumen, 15 Fr, step-tipped catheter designed for retrograde placement. The catheter is available in multiple lengths.

The catheters will be packaged sterile with various components to facilitate insertion.

5. **Indications for Use**

The Arrow NextStep® Retrograde Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow NextStep Retrograde Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are

intended for femoral vein insertion. The Arrow NextStep Retrograde catheter is intended for use in adult patients.

6. **Technological Characteristics and Substantial Equivalence**

The NextStep Retrograde catheter with expanded indications to add femoral indications and increased lengths is substantially equivalent to the Arrow NextStep Antegrade Chronic Hemodialysis Catheters (K111900) and the Arrow NextStep Retrograde Chronic Hemodialysis Catheter (K111117) in terms of overall design, manufacturing process, functional performance, and materials of construction. The indications for use, for the proposed catheter, are identical to the Arrow NextStep Antegrade Chronic Hemodialysis Catheter (long-term vascular access for hemodialysis and apheresis, placed in the internal jugular, subclavian or femoral veins). The intended use of the product and the principle of operation of the device is unchanged.

7. **Nonclinical Testing**

The dialysis flow rate, hemolysis, and additional testing that is needed to comply with *Draft Guidance for Industry and Food and Drug Administration Staff- Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis* was performed for the longer length catheters. Bench testing was previously completed on the predicate NextStep Retrograde catheters in accordance with ISO 10555-1 and 10555-3. Testing included biocompatibility (ISO 10993-1).

8. **Clinical Data**

Clinical performance data was not used to determine substantial equivalence.

9. **Conclusions**

The results of the testing performed have demonstrated that the proposed NSR catheters are safe and perform as intended and therefore are considered substantially equivalent to the cited predicate devices.

10. **Necessary Information**

At this time the 510k Summary includes the information deemed necessary by FDA.

11. **The following information has been met:**

- The summary includes only information that is covered in the body of the 510(k).
- The summary does not contain any puffery or unsubstantiated labeling claims.
- The summary does not contain any raw data.
- The summary does not contain any trade secret or confidential commercial information.
- The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 10, 2013

Arrow International, Inc.
% Ms. Gwen Taschner
Regulatory Affairs Specialist
2400 Bernville Road
READING PA 19605

Re: K130192
Trade/Device Name: Arrow NextStep® Retrograde Chronic Hemodialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: April 9, 2013
Received: April 12, 2013

Dear Ms. Taschner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K130192

Device Name: Arrow NextStep® Retrograde Chronic Hemodialysis Catheter

Indications for Use:

The Arrow NextStep® Retrograde Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow NextStep Retrograde Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow NextStep Retrograde catheter is intended for use in adult patients.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130192